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BUSH INTELLECTUAL PROPERTY LAW GROUP, LLC
P.O. BOX 381146
BIRMINGHAM, AL 35238

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,362	PARSONS, DIANA J.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23-29 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 23-29, 33-37.* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 11/22/06 is acknowledged. Claims 1-20, 22, and 30-32 stand cancelled. Claims 21, 23-29, 33-37 are pending.

Claim Rejections - 35 USC § 112

The rejection of claims 1-37 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendments of 11/22/06 and cancellation of claims 1-20.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 recites the limitation "the face" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The rejection of claims 1-4, 11, 14-16, 19-20 under 35 U.S.C. 102(b) as being anticipated by Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) is moot in view of the cancellation of the claims.

Claims 1-4, 11, 14-16, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) is moot in view of the cancellation of the claims.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 23, 26-29, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883).

Tankovich teaches a method of hair removal and skin treatment including treating herpes virus lesions and infections, treating scar tissue, and skin rejuvenation (see column 52, lines 10-30) utilizing laser therapy. See abstract. The procedure entails utilizing a contaminant such as a suspension of carbon particles in an oil- or water-based medium and illuminating the skin with laser pulses. A Q-switched Nd:YAG laser with a wavelength of 1064 nm is utilized in the process.

The method used for treating scars includes: applying a contaminant to keloid or hypertrophic scar tissue, and the area is irradiated by laser energy for about 5 or 6 passes, or until erythema or minor inflammation is detected in the scarred area. Then a period of about 4 to about 6 weeks is allowed to pass before the treatment is repeated. A total of from about 2 to about 8 treatments is generally sufficient to cause reorganization of the epithelial layer and removal of the scar. See column 58.

The parameters for treating the skin for hair removal includes using a Nd:YAG laser with a pulse frequency of 10 Hertz (10 pulses per second) and a fluence of about 2 to 3 J/cm2. see column 12, lines 45-20 and column 34, lines 5-20. The pulse frequency may be a combination of both short pulses (10 ns to about 30ns) and long pulses (100 microseconds to 100ms). Tankovich teaches the instant fluence of about 2.5 J/cm2 and a pulse duration of 10ns (0.01 microsecond). See column 30, lines 45-51 and column 49, lines 5-10 . The treatment should be scheduled every 2 to 3 weeks after the hair follicle has fallen out. See column 48, lines 34-55. The parameters for treating Herpes infections include wavelength of 1064nm, fluence of 1-2 J/cm2, and a pulse energy of 0.5 J/pulse. See column 45, lines 1-10 and column 43, lines 25-40. Tankovich teaches post-operative treatment of the targeted area includes any commonly accepted methods known to those in the medical arts.

Tankovich does not teach the instant pre-treatment or specify the post-treatment.

Ho et al teach laser resurfacing in pigmented skin and skin with acne scars with a CO2 laser. The method includes: (a) The patients were treated with 0.05% tretinoin, hydroquinone, and desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO2 laser with a setting of 250-450 mJ per pulse, or the Silk-Touch flashscanner at the setting of 5-7 W, 0.2-second pulse duration, and 4-mm (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Ho discloses the reduction of hyperpigmentation with regular use of tretinoin, hydroquinone, and desonide cream both pre- and postoperatively along with use of broad-spectrum sunscreen after treatments. See abstract.

Kye teaches a method of resurfacing pitted facial scars including acne scars, chicken pox scar, and small pox scars, with a pulsed Er:YAG laser. The method includes: step (a) prior to laser surgery, the patients are treated with 0.05% tretinoin (note 0.05% reads on about 0.1%) nightly for two to four weeks; step (b) the patient is then treated with Er:YAG laser at a setting of 500mJ/pulse and 3.5-4.5 Watts with a pulse frequency of 7-9 Hz. Kye discloses that after 4-6 laser passes, pinpoint bleeding occurred; step (c) two weeks after laser treatment % tretinoin and 1% hydrocortisone cream is applied for 2-4 weeks. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made of Tankovich and Ho et al and utilize a pre-treatment and post-treatment regimen prior to the laser therapy taught in Tankovich. One would have been motivated to do so since Ho teaches the reduction of hyperpigmentation after laser resurfacing is reduced with regular use of tretinoin, hydroquinone, and desonide cream, both pre- and postoperatively. Furthermore, a skilled artisan would have expected similar results and success in using Ho's' pre/post treatment step in Tankovich's laser therapy since Tankovich teaches the laser therapy to treat skin disorders such as scars and teaches the use of any post treatment known in the art. Therefore, a skilled artisan would have been motivated to utilize a pre and post treatment step to reduce hyperpigmentation.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at Kye and utilize tretinoin for as part of the pre-laser and post-laser regimen prior to the laser therapy. Kye, as well as Ho, establishes the state of the art wherein it is known and conventional to utilize retinoic acid as part of the pre-laser and post-laser regimen. hyperpigmentation.

With regard to step (d) in claim 21, Tankovich teaches repeating the laser process until sufficient results are obtained with regard to scars and Tankovich teaches repeating the laser process every two to three weeks for hair removal. Therefore, it is within the skill of an artisan to repeat laser therapy based on the desired result and maintenance for a certain cosmetic condition. For instance, with regard to hair removal, a skilled artisan would be motivated to maintain the treatment as long as required to maintain hair-free skin including at least once every twelve months or more depending on the hair growth pattern. With regard to skin rejuvenation taught by Tankovich, a skilled artisan would be motivated to maintain the treatment as long as required to maintain healthy and young skin including at least once every twelve months or more.

Response to Arguments

Applicant argues that Tankovich teaches the use of an Nd:YAG laser with a wavelength of 1064nm to remove scars. Applicant argues that Tankovich teaches passing the laser across the scar 5 to 6 times whereas the instant invention only requires a single pass across the skin. Applicant argues that Tankovich teaches destroying the scar tissue to remove the scar and the instant invention does not destroy the skin tissue. Thus, applicant argues that Tankovich does not teach the instant laser method. Applicant argues that although Tankovich teaches the use of short pulses, this is used to synchronize the hair growth and not for cosmetic benefit. Applicant argues that Tankovich teaches away from one or two pulses of a short duration with a wavelength of 1064nm and a 1-2 J/cm2.

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive. As acknowledged by applicant, Tankovich teaches removing scars by utilizing Nd:YAG laser with a wavelength of 1064nm using "short pulses". See column 59, lines 124.

Tankovich defines a "short" pulse having a fluence of about 2 to about 3 J/cm2 as a pulse with a duration of 10ns to about 30ns. See column 34, lines 5-15. The examiner notes that Tankovich teaches passing the laser 5-6 over the skin; however in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the number of laser passes wherein applicant argues that the instant invention only requires one laser pass whereas Tankovich requires 5-6 passes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, independent claim 21, neither recites the wavelength nor the fluence. Secondly, the examiner points out that the instant method does not exclude the process of removing skin. Meaning, the instant claims are broadly directed to the method of improving the appearance of skin" wherein removing excessive and unsightly scar tissue reads on the instant method as claimed.

Further, the examiner points to column 50, lines 20-60 wherein Tankovich teaches the "improved laser operating characteristics for hair follicle damage" is a Nd:YAG laser with a wave length of 1064nm wherein the fluence of about 2 to about 3 J/cm2 and a pulse duration of 10ns. The method of removing hair reads on the instant methodology of improving the appearance of skin since the removal of unwanted hair provides smooth skin, free from stubble. Note that smooth skin is a skin a sign of "youthful" skin. Thus, Tankovich teaches short pulses to remove hair.

Applicant argues that that although Tankovich teaches treating herpes infections with a wavelength of 1065nm, a fluence of 1-2 J/cm2, and a pulse energy of 0.5 J/pulse, there is no

suggestion of a cosmetic benefit from this treatment. The examiner points out that Tankovich teaches on column 43, lines 25-30 that "[I]nfections of Herpes Simplex (oral or genital) or Herpes Zoster virus can manifest as skin lesions and/or rash at almost any location on the body." Thus, clearly the treatment of herpes infection provides a cosmetic benefit by treating the skin lesions and rash.

Thus, as noted from the above discussion, Tankovich does not teach away from the use of short duration pulses as argued by applicant.

Applicant argues that Tankovich does not teach a pre- or post-treatment and the secondary reference does not cure this deficiency. Applicant argues that Ho's method produces resurfacing the skin by heating the skin which causes persistent erythema and Ho uses a pulse duration 200 times longer than the instant invention. Applicant argues that Ho does not teach the use of tretinoin as the sole pharmacologic agent to produce a cosmetic benefit. Applicant argues that the inventive concept is the use of the topical retinoic acid to produce a synergistic effect.

It is noted that applicant argues against the references individually and the examiner points out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case, the examiner only relies on Ho to teach the use of retinoic acid to treat the skin pre and post operatively and the fact that Ho uses a different pulse duration than claimed is irrelevant since the primary reference is not deficient in this sense. Tankovich clearly teaches the use of any post-operative treatment known to those skilled in the art. Thus, a skilled artisan would have been motivated to use retinoic acid to help reduce hyperpigmentation associated with laser

treatment. With regard to applicant's argument that the instant invention is unexpected since the retinoic acid and laser treatment provides a synergist effect, the examiner points out that the concept of using retinoic acid in conjunction with laser therapy is taught by Ho. For instance, Ho teaches the use of retinoic acid in conjunction with laser therapy reduces the risk of hyperpigmentation. Thus, Ho establishes that it is known to use laser therapy and retinoic acid together to treat skin conditions. Further, it is noted applicant has not provided any evidence of this synergistic effect.

Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al (6,050,990) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) in further view of Obagi (4,874,361).

The teachings of Tankovich and Ho have been delineated above.

The references do not specify the length of the laser treatment.

Obagi discloses a method of treating chronic skin problems (acne, wrinkles, pigmentation disorders) with laser treatment. Patients are treated with a composition that stimulate skin regeneration. After the composition is applied, the area is treated with light. The parameters chosen are dependent on the skin type (dark versus light), the type of peel (light versus deep), and severity of the skin condition. See column 5. However, usually the time range is 2-15 minutes with repeated treatments. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tankovich et al, Ho et al, and Obagi and manipulate the length of the laser treatment. One would be motivated to do so since Obagi discloses that the

length of treatment depends on several factors including skin color and type and severity of the condition but the time can only be in the order of minutes regardless of race. Therefore, the length of treatment is a manipulatable parameter which depends on the various factors, including the severity of the condition, skin type and color, and the area treated and Obagi discloses that it is within the skill of an ordinary artisan to manipulate this parameter (column 5).

Response to Arguments

Applicant has not addressed the above rejection specifically. The amendment to recite "the face" does not overcome the above rejection. The claims are rejected for the reasons set forth above.

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616